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WASHINGTON DC 20036-5405

HM22/0825

EXAMINER

FORMAN, B

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/242,561

Applicant(s)

SATO, YOSHIHIRO

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☐ Responsive to communication(s) filed on 19 June 2000.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. This action is in response to papers filed 19 June 2000 in Paper No. 6 in which claims 1-20 were canceled and new claims 21-39 were added. All of the arguments regarding the previous rejections have been thoroughly reviewed. The arguments are mooted in view of the canceled claims and new grounds for rejection. All previous rejections under 35 USC § 112, second paragraph, under 35 USC § 102 and under 35 USC § 103 are mooted in view of the canceled claims and new grounds for rejection. The new grounds for rejection are discussed below.
2. Currently claims 21-39 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

#### **First paragraph of 35 U.S.C. 112: Scope of Enablement**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 21-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a process for reducing evaporation during PCR comprising a glass substrate having an oily layer on top of the substrate and an aqueous droplet shot into the oily layer and onto the substrate wherein said oily layer surrounds all surfaces of said droplet which are not in contact with said substrate, does not reasonably provide enablement for a process for reducing evaporation comprising a substrate, liquid layer and minute droplet. The claims are recited in functional language i.e. describing the substrate, liquid layer and minute droplet in terms of what they do as opposed to what their composition is. The claims are written so broadly so as to encompass a myriad of compositions having the recited

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functions i.e. substrates, liquid layers and minute droplets. However, the specification teaches only one specific embodiment i.e. a glass slide or glass coverslip substrate (page 16, second paragraph and page 18, second and third paragraphs), an oily liquid layer (page 20, lines 5- page 22, line 2) and an aqueous droplet (page 21, line 6-page 22). The claims are extremely broad encompassing any and all substrate, liquid layer and droplet compositions and combinations of the compositions. In view of the state of the art wherein substrates are comprised of a myriad of compositions having numerous shapes, numerous sizes, numerous chemical compositions and an extremely large number of combinations of substrate size, shape and chemical composition and in view of the state of the art wherein liquid layers are comprised of a myriad of compositions having an extremely wide range of volumes comprising numerous chemical compositions and properties, numerous physical properties and numerous optical properties and in view of the state of the art wherein droplets are comprised of a myriad of compositions having a wide range of volumes comprising numerous chemical compositions and properties, numerous physical properties and numerous optical properties it would require one skilled in the art undue experimentation to analyze the infinite number of combinations of substrate, liquid layer and droplet compositions to make and use the claimed invention. In view of the nature of the invention wherein reducing evaporation requires specific physical and environmental conditions for obtaining the desired results and wherein a very limited number of the claimed substrate, liquid layer and droplet compositions would be expected to function cooperatively in the claimed method to obtain the desired results and wherein conducting a reaction requires extremely specific and exact physical, environmental and reagent conditions for obtaining the desired results and wherein an extremely limited number of the claimed substrate, liquid layer and droplet composition would be expected to function cooperatively in the claimed method to obtain the desired results it would require one skilled in the art undue experimentation to analyze the infinite number of combinations of substrate, liquid layer and droplet compositions to derive combinations of compositions which would function

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cooperatively in the claimed methods. In view of the level of predictability in the art wherein obtaining the desired "reducing evaporation" requires specific physical, chemical and environmental conditions and wherein obtaining the desired "reaction" requires extremely specific and exact physical, chemical and environmental conditions it would require one skilled in the art undue experimentation to analyze the infinite number of combinations of substrate, liquid layer and droplet compositions to obtain the desired "reducing evaporation" and "reaction". Additionally, the lack of working examples for the claimed methods wherein the specification teaches only one method i.e. PCR and one composition combination i.e. a glass slide or glass coverslip substrate, an oily liquid layer, and an aqueous droplet, it would require one skilled in the art an undue amount of experimentation to make and use the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is recommended that the claims be amended to claim the method and compositions as taught in the specification.

5. Claim 34-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a process for conducting a PCR reaction in a minute droplet protected from evaporation, does not reasonably provide enablement for a process for conducting any reaction. The claims are written so broadly so as to encompass a myriad of reactions. However, the specification teaches only the PCR reaction (page 3, last paragraph and pages 23-56). The claims are extremely broad encompassing any and all reactions. In view of the nature of the invention wherein "a reaction" comprises a myriad of reactions, comprising a myriad of reagents, reagent preparations, reaction conditions, environmental conditions and chemical conditions wherein each reaction requires specific and exact reagents, reagent preparations, reagent conditions, environmental conditions and chemical conditions to obtain the desired results and in view of the specification's teaching of only one reaction i.e.

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PCR, it would require undue experimentation for one skilled in the art to obtain the desired results in the myriad of claimed reactions. In view of the state of the art wherein "conducting a reaction" is dependent upon a large number of variables e.g. reagents, reagent temperature, physical environment, temperature & pH to obtain the desired results, it would require one skilled in the art undue experimentation to obtain the desired results in the myriad of claimed reactions. In view of the level of predictability in the art wherein the slightest change in reagents and conditions alter experimental results and wherein each and every reaction requires its own set of very specific reagents, reagent preparations, reaction conditions, environmental conditions and chemical conditions to obtain the desired results and in view of the specification's teaching of only one reaction i.e. PCR, it would require the skilled practitioner undue experimentation to obtain the desired results in the myriad of claimed reactions. Therefore, in view of the lack of working examples for the myriad of claimed reactions, it would require an undue amount of experimentation to make and use the invention as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is recommended that the claims be amended to claim the method as taught in the specification.

**Second paragraph of 35 U.S.C. 112: Indefinite**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 21-32 are indefinite in Claim 21 for being drawn to a “method for reducing evaporation of a minute droplet”, but the claim does not recite a method step wherein evaporation is reduced. It is suggested that the last line of Claim 21 be amended to recite “in contact with said substrate whereby evaporation is reduced.”

b. Claims 21-32 are indefinite in Claim 21, line 5 for the recitation “substantially immiscible” because “substantially” is a relative term which requires definition or criteria for determining. It is suggested that the claim be amended to clarify e.g. define or delete “substantially”.

c. Claims 21-32 are indefinite in Claim 21, for the descriptions of structural components in functional language i.e. “substrate”, “liquid layer” and “minute droplet” and therefore it is unclear what structural limitations are imposed on the structures and one of skill in the art would not be apprised of the scope of the claim. It is suggested that the claims be amended to recite structural limitations as described in the specification i.e. “planar glass substrate” “oily liquid layer” and “aqueous droplet”.

d. Claims 22, 24 & 28 are indefinite in the recitation “has water repellency” because it is unclear whether the substrate is water repellent. It is suggested the claim be amended to distinctly claim the subject matter i.e. replace “has water repellency” with “is water repellent”.

e. Claims 26 & 27 are indefinite because “to come into contact with said substrate” is redundant. It is suggested that the claims be amended to delete “to come into contact with said substrate”.

f. Claim 33 is indefinite in the recitation “substantially immiscible” because “substantially” is a relative term which requires definition or criteria for determining. It is suggested that the claim be amended to clarify e.g. define or delete “substantially”.

g. Claim 33 is indefinite in the descriptions of structural components in functional language i.e. “substrate”, “liquid layer” and “minute droplet” and therefore it is unclear what structural limitations are imposed on the structures and one of skill in the art would not be

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appraised of the scope of the claim. It is suggested that the claims be amended to recite structural limitations as described in the specification i.e. "planar glass substrate" "oily liquid layer" and "aqueous droplet".

h. Claims 34-39 are indefinite in Claim 34, for the descriptions of structural components in functional language i.e. "substrate", "liquid layer", "minute droplet" and "reactant" and therefore it is unclear what structural limitations are imposed on the structures and one of skill in the art would not be appraised of the scope of the claim. It is suggested that the claims be amended to recite structural limitations as described in the specification i.e. "planar glass substrate" "oily liquid layer" "aqueous droplet" and "PCR reagents".

i. Claims 34-39 are indefinite in Claim 34, lines 3 & 5 for the recitations "providing a substrate having a contact surface" and "providing a minute droplet in contact with said substrate" because it is unclear whether the droplet is in contact with the "contact surface" of the "substrate". It is suggested that line 5 of Claim 34 be amended to insert "contact surface of" in front of "substrate".

j. Claims 34-39 are indefinite in Claim 34, line 6 for the recitation "substantially immiscible" because "substantially" is a relative term which requires definition or criteria for determining. It is suggested that the claim be amended to clarify e.g. define or delete "substantially".

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary



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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 21- 36 & 39 are rejected under 35 U.S.C. 103(a) as obvious over Gelfand et al. , (U.S. Patent No.5,310,652, filed 24 June 1993).

Regarding Claim 21, Gelfand et al teach a process of reducing evaporation of a minute droplet comprising: providing a substrate i.e. tubes, providing a liquid layer i.e. mineral oil and providing a minute droplet in contact with said substrate i.e. PCR assay mix said droplet being immiscible with said liquid layer and wherein said liquid layer surrounds all surface of said droplet that are not in contact with said substrate (Column 33, lines 1-20). Gelfand et al. teach the method wherein said minute droplet is provided prior to the liquid layer. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. to obtain the claimed invention because one skilled in the art would have been motivated with a reasonable expectation of success to provide the liquid layer prior to the minute droplet for the obvious benefit of simultaneously applying the liquid layer to all substrates without risk of cross-contamination between samples and eliminating the sample-by-sample application of Gelfand et al.

Regarding Claim 22, Gelfand et al. teach the method wherein said substrate is a microfuge tube (Column 33, lines 1 & 17-20) but they do not teach the substrate has water repellency. However, microfuge tubes routinely used in the art were known to have water repellency to promote pelleting of solutes by repelling aqueous solutions away from the wall of the tube. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the microfuge tubes of Gelfand et al. with microfuge tubes having water repellency based on their known pelleting properties and for the expected benefit of pelleting and collecting solutes from the droplets of Gelfand et al.

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Regarding Claim 23, Gelfand et al teach the method wherein said droplet is aqueous and said liquid layer is oily (Column 33, lines 17-20).

Regarding Claim 24, Gelfand et al. teach the method wherein said substrate is a microfuge tube (Column 33, lines 1 & 17-20) but they do not teach the substrate has water repellency. However, microfuge tubes routinely used in the art were known to have water repellency to promote pelleting of solutes by repelling aqueous solutions away from the wall of the tube. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the microfuge tubes of Gelfand et al. with microfuge tubes having water repellency based on their known pelleting properties and for the expected benefit of pelleting and collecting solutes from the droplets of Gelfand et al.

Regarding Claim 25, Gelfand et al teach the method wherein said liquid layer consists of mineral oil (Column 25, lines 17-20).

Regarding Claim 26, Gelfand et al. teach the method of Claim 21 wherein said droplet is added to the substrate (Column 33, lines 15-17) but they do not teach said droplet is shot into said liquid layer. However, injection methods for droplet delivery wherein the droplet is "shot" (e.g. by ink jet) were known and routinely practiced in the art at the time the claimed invention was made. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply known droplet delivery methods to the method of Gelfand et al. for the known benefit of speed and accuracy of droplet delivery.

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Regarding Claim 27, Gelfand et al. teach the method of Claim 23 wherein said droplet is added to the substrate (Column 33, lines 15-17) but they do not teach said droplet is shot into said liquid layer. However, injection methods for droplet delivery wherein the droplet is "shot" (e.g. by ink jet) were known and routinely practiced in the art at the time the claimed invention was made. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply known droplet delivery methods to the method of Gelfand et al. for the known benefit of speed and accuracy of droplet delivery.

Regarding Claim 28, Gelfand et al. teach the method wherein said substrate is a microfuge tube (Column 33, lines 1 & 17-20) but they do not teach the substrate has water repellency. However, microfuge tubes routinely used in the art were known to have water repellency to promote pelleting of solutes by repelling aqueous solutions away from the wall of the tube. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the microfuge tubes of Gelfand et al. with microfuge tubes having water repellency based on their known pelleting properties and for the expected benefit of pelleting and collecting solutes from the droplets of Gelfand et al.

Regarding Claim 29-31, Gelfand et al. teach the method of Claims 21, 23, & 27 further comprising providing a covering over said liquid layer wherein said covering is the microfuge cap (Column 5, lines 33-34).

Regarding Claim 33, Gelfand et al teach a process of reducing evaporation of a minute droplet comprising: providing a substrate, providing a liquid layer, providing a minute droplet

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said droplet being immiscible with said liquid layer and providing a covering which is the tube cap, wherein said liquid layer surrounds all surface of said droplet that are not in contact with said substrate (Column 33, lines 1-20). Gelfand et al. do not teach the method wherein the said covering is in contact with said droplet. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify Gelfand et al. method to provide the covering in contact with said droplet for the obvious benefit of eliminating intervening air space and thereby preventing evaporation and condensation at elevated PCR temperatures.

Regarding Claim 34, Gelfand et al teach a process for conducting a reaction in a minute droplet protected from evaporation of a minute droplet comprising: providing a substrate, providing a liquid layer, providing a minute droplet said droplet being immiscible with said liquid layer, providing a covering wherein said liquid layer surrounds all surface of said droplet that are not in contact with said substrate, providing to said droplet a reactant and conducting a reaction in said droplet (Column 33, lines 1-20). Gelfand et al. do not teach the method wherein the said covering is in contact with said droplet. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify Gelfand et al. method to provide the covering in contact with said droplet for the obvious benefit of eliminating intervening air space and thereby preventing evaporation and condensation at elevated PCR temperatures.

Regarding Claim 35, Gelfand et al teach the method wherein said droplet is aqueous and said liquid layer is oily (Column 33, lines 17-20).

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Regarding Claim 36, Gelfand et al. teach the method wherein said aqueous droplet comprises DNA (Column 6, lines 29-33).

Regarding Claim 39, Gelfand et al. teach the method wherein the liquid layer is mineral oil (Column 33, lines 17-20) but they do not teach the liquid layer has a thickness of about 100 $\mu$ m or less. However, liquid layers of  $\mu$ m thickness were known and routinely practiced in the art at the time the claimed invention was made. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with routinely practiced procedures to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the liquid layer of Gelfand et al. with a layer having  $\mu$ m thickness for the obvious benefit of reducing reagent quantities and thereby costs.

10. Claims 37 & 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand et al. (U.S. Patent No.5,310,652, filed 24 June 1993) as applied to Claim 34 above and in view of Sambrook et al. (Molecular Cloning: A laboratory Manual, 2<sup>nd</sup> Ed., 1992).

Regarding Claims 37 & 38, Gelfand et al teach the method wherein the minute droplet comprises an enzyme adsorption preventing agent i.e. Tween 20<sup>TM</sup> (Column 32, lines 4-17), but they do not teach the method wherein the contact surface between said substrate and said minute droplet comprises the enzyme adsorption preventing agent (Claim 37) and the contact surface comprises a bovine serum albumin coating (Claim 38). The skilled practitioner in the art would have known that nucleic acid assays utilize the enzyme adsorption preventing agent SDS as taught by Sambrook et al. who teach that Denhardt's reagent which contains SDS is used in nucleic acid assays to block non-specific binding reactions and increase signal-to noise ratios (page 9.48) and bovine serum albumin to block non-specific nucleic acid binding to the surface of the substrate (page 9.47-9.48). It would have been *prima facie* obvious to one of

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ordinary skill in the art at the time the claimed invention was made to modify the method of Gelfand et al. with the teaching of Sambrook et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the Denhardt's reagent as taught by Sambrook et al. to the method of Gelfand et al. for the expected benefit of reducing non-specific binding and for the added benefit of commercial availability and convenience as a premixed solution. The skilled practitioner in the art would have been further motivated to coat the substrate surface in the method of Gelfand et al. for the benefit of reducing non-specific binding to the substrate as taught by Sambrook et al.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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### Conclusion


12. No claim is allowed. Claim 32 is free of the prior art of record and may be placed in condition for allowance following resolution of the above stated rejections.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
August 23, 2000

  
S. Zomer  
August 23, 2000